Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kit
510(k) Summary
21 CFR 807.92

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based as follows:

JAN 15 2008

1. Submitter Information:

Applicant:	Bard Peripheral Vascular, Inc 1625 West 3rd Street Tempe, Arizona 85281
Phone:	480-303-2524
Fax:	480-449-2546
Contact:	Genevieve Balutowski Associate Project Manager, Regulatory Affairs

2. Subject Device:

Device Trade Name:	**Recovery® G2® Filter System – Femoral Delivery Kit** and **Recovery® G2 Filter System – Jugular/Subclavian Delivery Kit**
Common or Usual Name:	Filter, Intravascular, Cardiovascular
Classification:	Class II
Classification Panel:	Cardiovascular

3. Predicate Devices:

G2™ Filter System – Femoral Delivery Kit (K062887)

G2™ Filter System – Jugular/Subclavian Delivery Kit (K052578)

4. Summary of Change:

The change to the predicate devices, G2™ Filter System – Femoral Delivery Kit and the G2™ Filter System – Jugular/Subclavian Delivery Kit, only affect the indications for use. Indications for use of the subject device, Recovery® G2® Filter System – Femoral and Jugular Delivery Kits, are identical to the indications for use of the predicate devices, with the exception of the last bullet point that notes:

"Recovery® G2® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal."

5. Device Description:

Recovery® G2® Filter System - Femoral and Jugular/Subclavian Delivery Kits

The Recovery® G2 Filter consists of 12, shape-memory nitinol wires emanating from a central nitinol sleeve. These 12 wires form two levels of emboli filtration: the legs provide the lower level of filtration and the arms provide the upper level of filtration. The Recovery® G2® Filter is intended to be used in the inferior vena cava with diameters less than or equal to 28 mm. The predicate device filter is identical to the subject device filter.

The Recovery® G2® Filter System – Femoral Delivery Kit consists of a 7 French I.D. introducer catheter and dilator set (Kit A) and a storage tube preloaded with the Recovery® G2® Filter and pusher system (Kit B). Kit A (introducer catheter and dilator) is used to gain access to the inferior vena cava via a femoral approach. The dilator accepts a 0.038" guidewire and the introducer catheter has 2 radiopaque marker bands on the distal end to assist in filter delivery. The pusher system (Kit B), designed to pass through the introducer catheter, consists of a grooved segment designed to hold and properly orient the filter legs and a flexible nitinol wire with a pad at the end that pushes on the filter apex.

The Recovery® G2® Filter System – Jugular/Subclavian Delivery Kit consists of a 10 French I.D. introducer sheath and dilator set and a delivery device preloaded with the Recovery® G2® Filter. The introducer sheath and dilator are used to gain access to the inferior vena cava via a jugular or subclavian approach. The dilator accepts a 0.038" guidewire and enables a contrast medium power injection up to 800 psi maximum pressure. The introducer sheath contains a radiopaque tip and hemostasis valve with a

side port for injecting contrast medium via a syringe. The delivery device fits within the introducer sheath and consists of a side port for saline infusion and a delivery mechanism to deploy the Recovery® G2® Filter. The delivery device contains a spline cap that mechanically separates the filter hooks from one another in a unique pattern to properly orient the filter legs and contains a pusher wire consisting of a flexible nitinol wire with a pad at the end that pushes on the filter sleeve.

6. Intended Use of Device:

The subject device, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits, is indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Recovery® G2® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

7. Performance Data:

The Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits were evaluated via data collected from bench and animal testing. Additionally, the safety of retrieval of the Recovery® G2® Filter was evaluated in a prospective, multi-center, non-randomized clinical study. Retrieval of the Recovery® G2® Filter was achieved in 95.1% of the study subjects undergoing a retrieval procedure. The mean filter indwell time in the retrieved subjects was 140.0 ± 62.1 days (median 143.5, range 5 – 300).

8. Technological Comparison to Predicate Device:

The technological characteristics of the subject device, the Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits, are substantially equivalent to

those of the predicate devices, the G2® Filter System – Femoral Delivery Kit and the G2® Filter System – Jugular/Subclavian Delivery Kit, in terms of intended use, application, user population, basic design, fundamental scientific technology, performance, and sterilization method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 15 2008

Bard Peripheral Vascular, Inc.
c/o Ms. Genevieve Balutowski
Senior Regulatory Affairs Specialist
P.O. Box 1740
Tempe, AZ 85280

Re: K073090
Trade Name: Recovery G2 Filter System – Femoral and Jugular/Subclavian Delivery Kits
Regulation Number: 21 CFR 870.3375
Regulation Name: Cardiovascular Intravascular Filter
Regulatory Class: Class II (two)
Product Code: DTK
Dated: October 31, 2007
Received: November 1, 2007

Dear Ms. Balutowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Brad D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073090

Device Name: Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits

Indications for Use:

The Recovery® G2® Filter System – Femoral and Jugular/Subclavian Delivery Kits are indicated for use in the prevention of recurrent pulmonary embolism via permanent placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulants are contraindicated.
- Failure of anticoagulant therapy for thromboembolic disease.
- Emergency treatment following massive pulmonary embolism where anticipated benefits of conventional therapy are reduced.
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.
- Recovery® G2® Filter may be removed according to the instructions supplied under the section labeled: Optional Procedure for Filter Removal.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part21 CFR 801 Subpart D) (21CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073090

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